

Exhibit 1

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to

All Cases

**LETTER OF REQUEST FOR
INTERNATIONAL JUDICIAL
ASSISTANCE TO THE
APPROPRIATE JUDICIAL
AUTHORITIES IN THE UNITED
KINGDOM**

The United States District Court for the District of Minnesota presents its compliments to the Senior Master of the High Court of Justice, Queen's Bench Division, Royal Courts of Justice, Strand, London WC2A 2LL and requests international judicial assistance for the production of documents to be used in a civil proceeding before this Court in the above-captioned matter. This Court requests the assistance described herein as necessary in the interests of justice. The assistance requested is for the appropriate judicial authority of the United Kingdom to compel the below-named individuals to submit to depositions and produce documents.

- David Leaper, University of Huddersfield, Queensgate, Huddersfield HD1 3DH;
- Andrew Legg, Chesterfield Royal Hospital, Chesterfield Rd, Calow, Chesterfield S44 5BL;
- Paul McGovern, University College London Hospitals NHS Foundation Trust 235 Euston Rd, Fitzrovia, London NW1 2BU; and
- Mike Reed, Northumbria Hospital Trust, North Tyneside General Hospital, Rake Ln, North Shields NE29 8NH.

The aforementioned individual[s] (collectively, “U.K. Authors”), nonparties to the above-captioned litigation, are material and necessary to aid in the resolution of the matter.

This Court affirms that:

1. This Letter of Request is sent to the High Court of Justice, Queen’s Bench Division, by the United States District Court for the District of Minnesota pursuant to, and in conformity with 28 U.S.C. § 1781, Article III of the Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, the Hague, 18 March 1970, the Evidence (Proceedings in Other Jurisdictions) Act 1975, and Part 34 of the English Civil Procedure Rules;

2. The requesting Court is a competent court in both law and equity, has jurisdiction over this action, and has the authority to compel the appearance of and the production of documents by corporations and individuals within its jurisdiction;

3. This request is issued pursuant to the rules and procedures applicable within this Court’s jurisdiction; and

4. The documents sought are relevant to the matters at issue in this action, are anticipated to be used at trial, are not available from any other source, and cannot be obtained without the assistance of the judicial authority of the United Kingdom.

In light of international law and the comity that exists between the United States and the United Kingdom, the undersigned respectfully issues this Letter of Request for international assistance. The requesting Court provides the additional information below in support of its request.

I. THE PARTIES AND THEIR REPRESENTATIVES

The defendants are 3M™ and Arizant Healthcare Inc. (“Defendants”), the designers and manufacturers of the Bair Hugger™ patient warming system (“Bair Hugger system”). Defendants are represented by:

Jerry W. Blackwell, Corey L. Gordon, and Peter J. Goss of Blackwell Burke, P.A., 431 South Seventh Street, Suite 2500, Minneapolis, MN 55415.

Bridget M. Ahmann and Christin Eaton Garcia of Faegre Baker Daniels LLP, 2200 Wells Fargo Center, 90 South Seventh Street, Minneapolis, MN 55402.

The plaintiffs (“Plaintiffs”) in the proceedings are patients who allegedly suffered infections while receiving surgical warming from the Bair Hugger system. Plaintiffs are represented by:

Co-Lead Counsel:

Michael V. Ciresi and Jan M. Conlin of Ciresi Conlin, LLP, 225 S. 6th St., Suite 4600, Minneapolis, MN 55402;

Anthony J. Nemo and Genevieve M. Zimmerman of Meshbeshier & Spence LTD, 1616 Park Avenue South, Minneapolis, MN 55404;

Ben W. Gordon, J. Michael Papantonio of Levin Papantonio, P.A., 316 S. Baylen Street, Suite 600, Pensacola, FL 32502-5996.

II. BACKGROUND

The Plaintiffs in this MDL litigation are patients who allegedly have experienced post-surgical infections and/or other medical complications following orthopedic or general surgery where a Bair Hugger™ patient warming system (“Bair Hugger system”) was used. [Master Long-Form Complaint, ¶¶ 20, 22, attached hereto as Exhibit 1] The

Bair Hugger system is an FDA-cleared medical device used to warm patients during surgery in order to maintain the patient’s normal body temperature. Plaintiffs allege that the Bair Hugger system caused their post-surgical infections and seek personal injury recovery against Defendants, who Plaintiffs allege designed, manufactured and marketed the Bair Hugger system used in their respective surgeries. [Master Long-Form Complaint, ¶¶ 23, 24]

In support of their allegations, Plaintiffs specifically cite to and rely on a number of scientific studies that allegedly “document[] the adverse effects of the Bair Hugger.” *Id.* at ¶¶ 62-63. These studies were authored by individuals residing in the United States, as well as individuals residing in the United Kingdom (“U.K.”). Defendants contend that they are entitled to discover any information the U.K. Authors have about the studies relied upon by Plaintiffs, because the study authors themselves disclaim any proof of causation within the context of any particular study.

III. THE INDIVIDUAL U.K. AUTHORS’ RELATIONSHIP WITH PLAINTIFFS AND DEFENDANTS

The U.K. Authors conducted research and published scientific studies relied upon by Plaintiffs in their suit against Defendants. Plaintiffs’ Master Long-Form Complaint specifically cites to these studies in support of their position that such studies “document[] the adverse effects of the Bair Hugger.” [Master Long-Form Complaint, ¶ 62] Certain of these studies were also discussed by Plaintiffs’ counsel and witnesses during Plaintiffs’ presentation at a Science Day before this Court. Plaintiffs will likely attempt to use these studies as evidence at trial. The Defendants plan to use these studies

to support their defense that the Plaintiffs lack scientific evidence that the Bair Hugger warming blanket causes or increases the risk of surgical site infections.

IV. REQUESTED EVIDENCE

In support of their defense in this lawsuit, Defendants request the following evidence from the U.K. Authors:

1. To take the testimony of each of the U.K. Authors on the topics specific in the attached Appendices A-1 through A-4;
2. The disclosure of documents specified within the attached Appendices B-1 through B-4, which are believed to be in the possession of each of the U.K. Authors.

Defendants contend that the study authors specifically deny that their studies establish that the Bair Hugger warming blanket causes surgical site infections. Because Plaintiffs rely on these studies to support their claims, Defendants submit that information in the possession of the U.K. authors about the design, procedures, conduct, data, and findings from the various scientific studies is highly relevant to this dispute and the proper subject of the letters rogatory process. On information and belief, the U.K. Authors possess documents about design, procedures, conduct, data, and findings from their studies.

After review, this Court has concluded that it is appropriate to seek international judicial assistance to facilitate the production of the requested documents because the requested documents are relevant, are anticipated to be used at trial, are not available

from any other source and cannot be obtained without the assistance of the judicial authorities of the United Kingdom.

V. PARTICIPATION IN DEPOSITIONS BY U.S. COUNSEL IS REQUESTED

Defendants request that you permit the questioning of the witnesses by the trial counsel in the action before this Court, as listed above. Defendants also request that all original documents provided pursuant to this process be produced for inspection by the Parties at the offices of Faegre Baker Daniels, 7 Pilgrim Street, London, EC4V 6LB, England, or some other place mutually agreeable to the parties, seven days prior to the depositions of witnesses.

Defendants further request that the Court issue its decision on this Request, and notice of the time and place for examination of the witnesses and the production of documents, to this Court and to counsel for Defendants as indicated above. Defendants further request that you order the examination under oath and appoint an Examiner to oversee the examination of the witnesses concerning the matters listed in the attached Appendices A-1 through A-4 at a place and time to be determined by the Examiner.

VI. DISCUSSION

The United Kingdom and the United States are both signatories to the Hague Convention. The Study Authors in question here are not parties to this litigation, are believed to be citizens and residents of the United Kingdom and not subject to the jurisdiction of this Court. Thus, the procedures of the Hague Convention are the only means by which the requested evidence may be obtained.

The Court finds that letters rogatory are appropriate in this case because the requests are narrowly tailored to information that is relevant to its defense and necessary for the presentation of its case. These requests are described in full in the attached appendices.

The evidence that the Defendants seek from the U.K. Authors is not available from other sources. The documents requested are the U.K. Authors' own documents and records. These documents are specific to, and in the exclusive possession of, these individuals. Therefore, in the interests of justice, international judicial assistance is needed to assure the production of this evidence from the U.K. Authors.

VII. REIMBURSEMENT OF COSTS

The Defendants agree to pay and undertake to reimburse any costs and expenses associated with this Request incurred by the Court in executing the same, as well as all reasonable costs and expenses associated with compliance by the witnesses with the Court's Order to the extent permitted or allowed under your law and procedure, or which the Court otherwise deems required under the circumstances.

VIII. RECIPROCITY

The requesting Court stands ready and willing to do the same for the courts of the United Kingdom if and when requested.

Dated: _____, 2016

The Honorable Joan N. Ericksen
United State District Judge
District of Minnesota

**Appendix A-1 for Dr. David J. Leaper
Testimony to Be Given**

Background

1. Name, address, and date of birth.
2. Education and employment history.
3. Use of and knowledge about patient warming devices.
4. Factors that influence infection for general and orthopedic surgery.
5. Infection control practices.
6. Experience designing, conducting, and writing manuscripts for the following studies:
 - a. Albrecht, Mark, et al. "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 (hereinafter "Albrecht 2011").
 - b. Leaper, David, Mark Albrecht, and Robert Gauthier. "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28 (hereinafter "Leaper 2009").
 - c. Wood, A. M., et al. "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140 (hereinafter "Wood 2014").

Roles and Arrangements for the Studies Described in Albrecht 2011, Leaper 2009 and Wood 2014

7. Your role in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Albrecht 2011, Leaper 2009 and Wood 2014.
8. The identity of and roles played by others in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Albrecht 2011, Leaper 2009 and Wood 2014.
9. Communications with others involved in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Albrecht 2011, Leaper 2009 and Wood 2014.
10. Communications with Dr. Scott Augustine about the studies described in Albrecht 2011, Leaper 2009 and Wood 2014.

11. Communications with Augustine Temperature Management about the studies described in Albrecht 2011, Leaper 2009 and Wood 2014.
12. Communications with the hospitals and locations where the studies described in Albrecht 2011, Leaper 2009 and Wood 2014 were performed.

Design, Materials, and Methods for the Studies Described in Albrecht 2011 and Leaper 2009

13. Details of and reasons for selecting locations, protocols, procedures, materials, and methods used in the studies described in Albrecht 2011 and Leaper 2009.
14. Selection, procurement, and condition of the operating theatres, patient warming devices, and other equipment used in the studies described in Albrecht 2011 and Leaper 2009.
15. Proposed and final study designs for the studies described in Albrecht 2011 and Leaper 2009, and the rationales for changes to study designs and protocols.
16. The carrying out of the studies described in Albrecht 2011 and Leaper 2009, and changes to protocols and practices during the conduct of those studies.
17. All measurements taken and data collected in the studies described in Albrecht 2011 and Leaper 2009.
18. Photographs or video recordings taken in connection with the studies described in Albrecht 2011 and Leaper 2009.

Study Results and Analysis

19. Statistical analysis of the raw data obtained in the studies described in Albrecht 2011 and Leaper 2009.
20. Preparation of the manuscripts for Albrecht 2011, Leaper 2009 and Wood 2014, including the roles of co-authors.
21. Reviewer comments for Albrecht 2011, Leaper 2009 and Wood 2014, including communications with co-authors regarding reactions and responses to reviewer comments.
22. Interpretation of the results of Albrecht 2011 and Leaper 2009.

23. Application of results of Albrecht 2011 and Leaper 2009 to hospital practices and patient safety.
24. Limitations of the designs, results and conclusions of Albrecht 2011, Leaper 2009 and Wood 2014, including the roles of co-authors.

Information About Other Studies

25. Information about the funding, selection of operating rooms, selection and procurement of patient warming devices, condition of patient warming devices, arrangements, design, conduct, results, analysis, limitations, peer review comments or publication of the studies described in these articles:
 - Melling, Andrew C., et al. "Effects of preoperative warming on the incidence of wound infection after clean surgery: a randomized controlled trial." *The Lancet* 358.9285 (2001): 876-880.
 - Wong, P. F., et al. "Randomized clinical trial of perioperative systemic warming in major elective abdominal surgery." *British Journal of Surgery* 94.4 (2007): 421-426.
 - Leaper, David J., et al. "Surgical site infection: poor compliance with guidelines and care bundles." *International wound journal* 12.3 (2015): 357-362.
 - Leaper, David, and Karen Ousey. "Evidence update on prevention of surgical site infection." *Current opinion in infectious diseases* 28.2 (2015): 158-163.
 - Ousey, Karen J., et al. "Perioperative warming therapy for preventing surgical site infection in adults undergoing surgery." *The Cochrane Library* (2015).
 - Tanner, J., et al. "Effectiveness of a care bundle to reduce surgical site infections in patients having open colorectal surgery." *The Annals of The Royal College of Surgeons of England* 98.4 (2016): 270-274.
 - Dasari, K. B., M. Albrecht, and M. Harper. "Effect of forced-air warming on the performance of operating theatre laminar flow ventilation." *Anaesthesia* 67.3 (2012): 244-249.
 - John, M., J. Ford, and M. Harper. "Peri-operative warming devices: performance and clinical application." *Anaesthesia* 69.6 (2014): 623-638.
 - Belani, Kumar G., et al. "Patient warming excess heat: the effects on orthopedic operating room ventilation performance." *Anesthesia & Analgesia* 117.2 (2013): 406-411.
 - Reed, Mike, et al. "Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions." *AANA J* 81.4 (2013): 275-280.
 - McGovern, P. D., et al. "Forced-air warming and ultra-clean ventilation do not mix." *J Bone Joint Surg Br* 93.11 (2011): 1537-1544.
 - Legg, A. J., T. Cannon, and A. J. Hamer. "Do forced air patient-warming devices disrupt unidirectional downward airflow?." *J Bone Joint Surg Br* 94.2 (2012): 254-256.
 - Legg, A. J., and A. J. Hamer. "Forced-air patient warming blankets disrupt unidirectional airflow." *Bone Joint J* 95.3 (2013): 407-410.
 - Huang, Joseph KC, et al. "The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk?." *Critical Care* 7.3 (2003): 1.

- Leaper, D. J., and A. G. Melling. "Antibiotic prophylaxis in clean surgery: clean non-implant wounds." *Journal of Chemotherapy* 13.sup2 (2001): 96-101.
- Leaper, David, and Cardiff Medicentre. "Maintaining Normothermia During Surgery."

US.107059807.01

**Appendix A-2 for Dr. Andrew J. Legg
Testimony To Be Given**

Background

1. Name, address, and date of birth.
2. Education and employment history.
3. Use of and knowledge about patient warming devices.
4. Factors that influence infection for general and orthopedic surgery.
5. Infection control practices.
6. Experience designing, conducting, and writing manuscripts for the following studies:
 - “Do forced air patient-warming devices disrupt unidirectional downward airflow?,” published in the Journal of Bone & Joint Surgery (Britain), 2012 Feb;94(2):254-6 (hereafter “Legg, Cannon, & Hamer”).
 - Communications between you and A.J. Hamer regarding the study that was described in the article titled “Forced-air patient warming blankets disrupt unidirectional airflow” in the Bone & Joint Journal, 2013 Mar.; 95-B(3):407-10 (hereafter “Legg & Hamer”).

Roles and Arrangements for the Studies Described in Legg, Cannon, & Hamer and Legg & Hamer

7. Your role in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
8. The identity of and roles played by others in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
9. Communications with others involved in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
10. Communications with Dr. Scott Augustine about the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
11. Communications with Augustine Temperature Management about the studies described in Legg, Cannon, & Hamer and Legg & Hamer.

12. Communications with the hospitals and locations where the studies described in Legg, Cannon, & Hamer and Legg & Hamer were performed.

Design, Materials, and Methods for the Studies Described in McGovern et al., Belani et al., and Reed et al.

13. Details of and reasons for selecting locations, protocols, procedures, materials, and methods used in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
14. Selection, procurement, and condition of the operating theatres, patient warming devices, and other equipment used in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
15. Proposed and final study designs for the studies described in Legg, Cannon, & Hamer and Legg & Hamer, and the rationales for changes to study designs and protocols.
16. The carrying out of the studies described in Legg, Cannon, & Hamer and Legg & Hamer, and changes to protocols and practices during the conduct of those studies.
17. All measurements taken and data collected in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
18. Photographs or video recordings taken in connection with the studies described in Legg, Cannon, & Hamer and Legg & Hamer.

Study Results and Analysis

19. Statistical analysis of the raw data obtained in the studies described in Legg, Cannon, & Hamer and Legg & Hamer.
20. Preparation of the manuscripts for Legg, Cannon, & Hamer and Legg & Hamer, including the roles of co-authors.
21. Reviewer comments for Legg, Cannon, & Hamer and Legg & Hamer, including communications with co-authors regarding reactions and responses to reviewer comments.
22. Interpretation of the results of Legg, Cannon, & Hamer and Legg & Hamer.
23. Application of results of Legg, Cannon, & Hamer and Legg & Hamer to hospital practices and patient safety.
24. Limitations of the designs, results, and conclusions of Legg, Cannon, & Hamer and Legg & Hamer.

Information About Other Studies

25. Information about the funding, selection of operating rooms, selection and procurement of patient warming devices, condition of patient warming devices, arrangements, design, conduct, results, analysis or publication of the studies described in these articles:
- Albrecht, M., et. al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009; 1:e28
 - Albrecht, M., et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011; 39:321-28
 - Dasari, K., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012; 67:244-49
 - McGovern, P., et al. Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics. *J Bone Joint Surg. (Br.)* 2011; 93(11):1537-44
 - Belani, K., et al., Patient warming excess heat: the effects on orthopedic operating room ventilation performance. *Anesthesia Analgesia* 2013; 117(2):406-11
 - Reed, M., et al. Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions. *AANA J* 2013; 81(4):275-80.
 - Wood, A., et al. Infection control hazards associated with the use of forced-air warming in operating theatres. *J Hosp Infect.* 2014;1-9

US.107059735.01

**Appendix A-3 for Dr. Paul McGovern
Testimony To Be Given**

Background

1. Name, address, and date of birth.
2. Education and employment history.
3. Use of and knowledge about patient warming devices.
4. Factors that influence infection for general and orthopedic surgery.
5. Infection control practices.
6. Experience designing, conducting, and writing manuscripts for the following studies:
 - “Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics,” published in the Journal of Bone and Joint Surgery (British) 2011 Nov.; 93(11):1537-44 (hereafter “McGovern et al.”).
 - “Patient warming excess heat: the effects on orthopedic operating room ventilation performance,” published in Anesthesia Analgesia 2013 Aug.; 117(2):406-11 (hereafter “Belani et al.”).
 - “Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions,” published in the AANA Journal, 2013 Aug.; 81(4):275-80 (hereafter “Reed et al.”).

Roles and Arrangements for the Studies Described in McGovern et al., Belani et al., and Reed et al.

7. Your role in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in McGovern et al., Belani et al., and Reed et al.
8. The identity of and roles played by others in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in McGovern et al., Belani et al., and Reed et al.
9. Communications with others involved in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in McGovern et al., Belani et al., and Reed et al.
10. Communications with Dr. Scott Augustine about the studies described in McGovern et al., Belani et al., and Reed et al.

11. Communications with Augustine Temperature Management about the studies described in McGovern et al., Belani et al., and Reed et al.
12. Communications with the hospitals and locations where the studies described in McGovern et al., Belani et al., and Reed et al. were performed.

Design, Materials, and Methods for the Studies Described in McGovern et al., Belani et al., and Reed et al.

13. Details of and reasons for selecting locations, protocols, procedures, materials, and methods used in the studies described in McGovern et al., Belani et al., and Reed et al.
14. Selection, procurement, and condition of the operating theatres, patient warming devices, and other equipment used in the studies described in McGovern et al., Belani et al., and Reed et al. studies described in McGovern et al., Belani et al., and Reed et al.
15. Proposed and final study designs for the studies described in McGovern et al., Belani et al., and Reed et al., and the rationales for changes to study designs and protocols.
16. The carrying out of the studies described in McGovern et al., Belani et al., and Reed et al., and changes to protocols and practices during the conduct of those studies.
17. All measurements taken and data collected in the studies described in McGovern et al., Belani et al., and Reed et al.
18. Photographs or video recordings taken in connection with the studies described in McGovern et al., Belani et al., and Reed et al.

Study Results and Analysis

19. Statistical analysis of the raw data obtained in the studies described in McGovern et al., Belani et al., and Reed et al.
20. Preparation of the manuscripts for McGovern et al., Belani et al., and Reed et al., including the roles of co-authors.
21. Reviewer comments for McGovern et al., Belani et al., and Reed et al., including communications with co-authors regarding reactions and responses to reviewer comments.
22. Interpretation of the results of McGovern et al., Belani et al., and Reed et al.
23. Application of results of McGovern et al., Belani et al., and Reed et al. to hospital practices and patient safety.
24. Limitations of the designs, results, and conclusions of McGovern et al., Belani et al., and Reed et al.

Information About Other Studies

25. Information about the funding, selection of operating rooms, selection and procurement of patient warming devices, condition of patient warming devices, arrangements, design, conduct, results, analysis or publication of the studies described in these articles:

- Albrecht, M., et. al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009; 1:e28
- Albrecht, M., et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011; 39:321-28
- Dasari, K., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012; 67:244-49
- Legg, A., et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone and Joint Surg.-Br.*, 2012; 94-B:254-56
- Legg, A., et al. Forced-air patient warming blankets disrupt unidirectional airflow. *Bone Joint J.* 2013; 95-B:407-10
- Wood, A.,et al. Infection control hazards associated with the use of forced-air warming in operating theatres. *J Hosp Infect.* 2014;1-9

US.107059647.01

**Appendix A-4 for Dr. Mike R. Reed
Testimony To Be Given**

Background

1. Name, address, and date of birth.
2. Education and employment history.
3. Use of and knowledge about patient warming devices.
4. Factors that influence infection for general and orthopedic surgery.
5. Infection control practices.
6. Experience designing, conducting, and writing manuscripts for the following studies:
 - “Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics,” published in the Journal of Bone and Joint Surgery (British), 2011 Nov.; 93(11):1537-44 (hereafter “McGovern et al.”).
 - “Patient warming excess heat: the effects on orthopedic operating room ventilation performance,” published in Anesthesia Analgesia, 2013 Aug.; 117(2):406-11 (hereafter “Belani et al.”).
 - “Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions,” published in the AANA Journal, 2013 Aug.; 81(4):275-80 (hereafter “Reed et al.”).
 - “Infection control hazards associated with the use of forced-air warming in operating theatres,” published in the Journal of Hospital Infection, 2014 Nov; 88(3):132-40 (hereafter “Wood et al.”).

Roles and Arrangements for the Studies Described in McGovern et al., Belani et al., Reed et al., and Wood et al.

7. Your role in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al.
8. The identity of and roles played by others in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al.
9. Communications with others involved in obtaining funding, designing, conducting, collecting data, analyzing results, and writing manuscripts for the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al.

10. Communications with Dr. Scott Augustine about the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al.
11. Communications with Augustine Temperature Management about the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al.
12. Communications with the hospitals and locations where the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al. were performed.

Design, Materials, and Methods for the Studies Described in McGovern et al., Belani et al., Reed et al., and Wood et al.

13. Details of and reasons for selecting locations, protocols, procedures, materials, and methods used in the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al.
14. Selection, procurement, and condition of the operating theatres, patient warming devices, and other equipment used in the studies described in McGovern et al., Belani et al., and Reed et al.
15. Proposed and final study designs for the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al., and the rationales for changes to study designs and protocols.
16. The carrying out of the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al., and changes to protocols and practices during the conduct of those studies.
17. All measurements taken and data collected in the studies described in McGovern et al., Belani et al., Reed et al., and Wood et al.
18. Photographs or video recordings taken in connection with the studies described in McGovern et al., Belani et al., and Reed et al.

Study Results and Analysis

19. Statistical analysis of the raw data obtained in the studies described in McGovern et al., Belani et al., and Reed et al.
20. Preparation of the manuscripts for McGovern et al., Belani et al., Reed et al., and Wood et al., including the roles of co-authors.
21. Reviewer comments for McGovern et al., Belani et al., Reed et al., and Wood et al., including communications with co-authors regarding reactions and responses to reviewer comments.
22. Interpretation of the results of McGovern et al., Belani et al., and Reed et al.

23. Application of results of McGovern et al., Belani et al., Reed et al., and Wood et al. to hospital practices and patient safety.
24. Limitations of the designs, results, and conclusions of McGovern et al., Belani et al., Reed et al., and Wood et al.

Information About Other Studies

25. Information about the funding, selection of operating rooms, selection and procurement of patient warming devices, condition of patient warming devices, arrangements, design, conduct, results, analysis or publication of the studies described in these articles:
 - Albrecht, M., et al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009; 1:e28
 - Albrecht, M., et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011; 39:321-28
 - Dasari, K., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012; 67:244-49
 - Legg, A., et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone and Joint Surg.-Br.*, 2012; 94-B:254-56
 - Legg, A., et al. Forced-air patient warming blankets disrupt unidirectional airflow. *Bone Joint J.* 2013; 95-B:407-10

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Appendix B-1
Request for Documents to Dr. David J. Leaper

Defendants 3M Company and Arizant Healthcare, Inc. request that the documents described below be produced by Dr. Leaper.

Documents To Be Produced

Dr. Leaper's Background

1. Your curriculum vitae or resume.

Documents Relating to Study Initiation and Protocols, Materials, and Methods

2. Communications between and among you and Augustine Biomedical + Design regarding the subject of funding for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
3. Communications between and among you and Dr. Scott Augustine regarding the subject of funding for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
4. Communications between and among you and Augustine Biomedical + Design regarding the subject of funding for the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
5. Communications between and among you and Dr. Scott Augustine regarding the subject of funding for the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
6. Communications between you and Augustine on the subject of funding of the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
7. Communications between you and Augustine Biomedical on the subject of funding of the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
8. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Biomedical + Design for your work on the study described in the article by David

Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.

9. Records of consulting fees, expense reimbursement, and other compensation paid to you by Dr. Scott Augustine for your work on the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
10. Agreements between you and Augustine Biomedical + Design for your work on the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
11. Agreements between you and Dr. Scott Augustine for your work on the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
12. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Biomedical + Design for your work on the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
13. Records of consulting fees, expense reimbursement, and other compensation paid to you by Dr. Scott Augustine for your work on the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
14. Agreements between you and Augustine Biomedical + Design for your work on the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
15. Agreements between you and Dr. Scott Augustine for your work on the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
16. Communications between you and the "hospitals in the vicinity of Minneapolis and St. Paul" regarding the forced air warming blowers used in the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.

17. Communications between you and the “hospitals in the vicinity of Minneapolis and St. Paul” regarding the operating rooms used in the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
18. Communications between you and the “hospitals in the vicinity of Minneapolis and St. Paul” regarding any other matters related to the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
19. Documents evidencing consent by the “hospitals in the vicinity of Minneapolis and St. Paul” for the conducting of the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
20. Documents evidencing consent by the “hospitals in the vicinity of Minneapolis and St. Paul” for the conducting of the study in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
21. Communications between you and the “hospitals in the vicinity of Minneapolis and St. Paul” regarding the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328, before the study was conducted.
22. Documents related to bacterial screening protocols (for the five years preceding the commencement of the study) at the “hospitals in the vicinity of Minneapolis and St. Paul” that were used for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
23. Documents related to patient warming protocols (for the five years preceding the commencement of the study) at the “hospitals in the vicinity of Minneapolis and St. Paul” that were used for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
24. Documents related to surgical skin preparation protocols (for the five years preceding the commencement of the study) at the “hospitals in the vicinity of Minneapolis and St. Paul” that were used for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
25. Documents related to wound dressing protocols (for the five years preceding the commencement of the study) at the “hospitals in the vicinity of Minneapolis and St. Paul” that were used for the study described in the article by David Leaper, Mark Albrecht and

Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.

26. Model and serial numbers for all forced air warming devices used in the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
27. Model and serial numbers for all forced air warming devices from which filters were taken for use in the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
28. Model and serial numbers for all forced air warming devices from which internal air path surface swabs were taken in the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
29. Model and serial numbers for all forced air warming devices for which hose outlet particle counts were performed in the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
30. Communications between and among you and the other authors of the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28 on the subject obtaining forced air warming devices for the study described in the article.
31. Communications between and among you and the other authors of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 on the subject obtaining forced air warming devices for the study described in the article.
32. All specifications for the ventilation systems of the operating rooms where you performed testing on the forced air warming devices in the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
33. All specifications for the ventilation systems of the operating rooms where you performed testing on the forced air warming devices for the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.

34. Final protocols for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
35. Final protocols for the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
36. Communications between you and Pace Analytical in Oakdale, Minnesota regarding their microbiological culturing and analysis performed for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
37. Documents exchanged between you and Pace Analytical in Oakdale, Minnesota regarding their microbiological culturing and analysis performed for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
38. Documents reflecting the purchase of the "five new intake filters" that were "obtained directly from the manufacturer" as described on page 321 of (and for use in the study described in) the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
39. Communications with "the manufacturer" of the "five new intake filters" described on page 321 of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328, about the filters.
40. Communications with "the manufacturer" of the "five new intake filters" described on page 321 of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328, about the study described in the article.
41. Protocol for placement of the particle counters in the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
42. Protocols for placement of the vacuums, mounting plate and internal particle sampling pitot tube used in and identified on page 322 of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.

43. Protocols for measuring the number of colony-forming units per swab in the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
44. Protocols for taking and recording measurements in the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
45. Statistical Analysis Plan for the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328, including the covariance model identified on page 324.
46. The plan for the statistical analysis described on page 86 of the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
47. Final criteria for the literature review described in the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
48. Communications between and among you and the other authors of the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140, regarding the results of the literature review described in the article.

Data from and Results of the Studies

49. All raw data generated during implementation of the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28, including data concerning swabbing and rinsing of the internal hose surfaces of the forced air warming devices used in the study.
50. All raw data generated during implementation of the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.

51. All graphic representations generated using data from the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
52. All graphic representations generated using data from the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
53. All results from the statistical analysis of raw data from the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
54. All results from the statistical analysis of raw data from the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
55. All photographs taken during implementation of the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28, including during set-up of the study.
56. All photographs taken during implementation the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328, including during set-up of the study.
57. All video or audio recordings made during the implementation of the study described in the article by David Leaper, Mark Albrecht, and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28, including during set-up of the study.
58. All video or audio recordings made during the implementation of the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328, including during set-up of the study.
59. Records reflecting all measurements taken during the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28, including during set-up of the study.

60. Records reflecting all measurements taken during the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328, including during set-up of the study.
61. Communications between and among you and the other authors of the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28 regarding the results of the study.
62. Communications between and among you and the other authors of the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 regarding the results of the study.
63. Communications between and among and you and Augustine Biomedical + Design regarding raw data for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
64. Communications between and among and you and Augustine Biomedical + Design regarding results of the data for the study described in the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
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67. Communications between and among and you and Augustine Biomedical + Design regarding raw data for the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 regarding the results of the study.
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room." *American journal of infection control* 39.4 (2011): 321-328 regarding the results of the study.

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70. Communications between and among and you and Dr. Scott Augustine regarding results of the data for the study described in the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 regarding the results of the study.

Study Publication

71. All pre-publication drafts and manuscripts of the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
72. All pre-publication drafts and manuscripts of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
73. All pre-publication drafts and manuscripts of the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
74. Communications between and among you and the other authors of the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28 regarding drafting of the article.
75. Communications between and among you and the other authors of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 regarding drafting of the article.
76. Communications between you and Augustine Biomedical + Design regarding the drafting of the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.

77. Communications between you and Dr. Scott Augustine regarding the drafting of the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
78. Communications between you and Augustine Biomedical + Design regarding the drafting of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 regarding drafting of the article.
79. Communications between you and Dr. Scott Augustine regarding the drafting of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328 regarding drafting of the article.
80. Communications between and among you and the other authors of the article A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140 regarding drafting of the article.
81. All communications from reviewers of the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
82. All communications from reviewers of the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
83. All communications from reviewers of the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
84. Communications between you and Orthopedic Reviews regarding the article by David Leaper, Mark Albrecht and Robert Gauthier titled "Forced-air warming: a source of airborne contamination in the operating room?." *Orthopedic reviews* 1.2 (2009): 28.
85. Communications between you and the American Journal of Infection Control regarding the article by Mark Albrecht, Robert Gauthier, Kumar Belani, Mark Litchy and David Leaper titled "Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room." *American journal of infection control* 39.4 (2011): 321-328.
86. Communications between you and the Journal of Hospital Infection regarding the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control

hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.

87. Communications between you and Augustine regarding the results of the literature review described in the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
88. Communications you and Augustine Biomedical regarding the results of the literature review described in the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
89. Communications between you and Augustine regarding the drafting of the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.
90. Communications between you and Augustine Biomedical regarding the drafting of the article by A.M. Wood, C. Moss, A. Keenan, M.R. Reed and D.J. Leaper titled "Infection control hazards associated with the use of forced-air warming in operating theatres." *Journal of Hospital Infection* 88.3 (2014): 132-140.

Communications with Counsel

91. Communications or correspondence between you and any lawyer or solicitor representing 3M in connection with the subject litigation pending in the United States.
92. Communications or correspondence between you and any lawyer or solicitor representing any plaintiff in connection with the subject litigation pending in the United States.

Appendix B-2
Request for Documents to Andrew J. Legg, BSc, MB ChB, FRCS

Defendants 3M Company and Arizant Healthcare, Inc. request that the documents described below be produced by Dr. Legg.

Documents To Be Produced

Dr. Legg's Background

1. Your curriculum vitae or resume.

Documents Relating to Study Initiation and Protocols, Materials, and Methods

2. Communications between and among you, A.J. Hamer, and T. Cannon regarding the study that was described in the article titled "Do forced air patient-warming devices disrupt unidirectional downward airflow?," published in the Journal of Bone & Joint Surgery (Britain), 2012 Feb;94(2):254-6 (hereafter "Legg, Cannon, & Hamer").
3. Communications between you and A.J. Hamer regarding the study that was described in the article titled "Forced-air patient warming blankets disrupt unidirectional airflow" in the Bone & Joint Journal, 2013 Mar.; 95-B(3):407-10 (hereafter "Legg & Hamer").
4. Communications between and among you and A.J. Hamer on the subject of funding for the study described in Legg & Hamer.
5. Communications between and among you, A.J. Hamer, and T. Cannon on the subject of funding for the study described in Legg, Cannon, & Hamer.
6. Communications between you and A.J. Hamer on the subject of obtaining patient warming devices for the study described in Legg & Hamer.
7. Communications between and among you, A.J. Hamer, and T. Cannon on the subject of obtaining patient warming devices for the study described in Legg, Cannon, & Hamer.
8. Communications between you and A.J. Hamer on the subject of the design of the study described in Legg & Hamer.
9. Communications between and among and you, A.J. Hamer, and T. Cannon on the subject of the design of the study described in Legg, Cannon, & Hamer.
10. Communications between you and Scott Augustine on the subject of the design of the study described in Legg & Hamer.
11. Communications between you and Scott Augustine on the subject of the design of the study described in Legg, Cannon, & Hamer.

12. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Legg & Hamer.
13. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Legg, Cannon, & Hamer.
14. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Legg & Hamer.
15. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Legg, Cannon, & Hamer.
16. Communications between you and Scott Augustine on the subject of funding of the study described in Legg & Hamer.
17. Communications between you and Scott Augustine on the subject of funding of the study described in Legg, Cannon, & Hamer.
18. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Legg & Hamer.
19. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Legg, Cannon, & Hamer.
20. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Legg & Hamer.
21. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Legg, Cannon, & Hamer.
22. Communications between you and Scott Augustine regarding the implementation of the study described in Legg & Hamer.
23. Communications between you and Scott Augustine regarding the implementation of the study described in Legg, Cannon, & Hamer.
24. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Legg & Hamer.
25. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Legg, Cannon, & Hamer.
26. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Legg & Hamer.
27. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Legg, Cannon, & Hamer.

28. Communications between you and Northern General Hospital, Sheffield, UK regarding the study described in Legg & Hamer.
29. Communications between you and Northern General Hospital, Sheffield, UK regarding the study described in Legg, Cannon, & Hamer.
30. Model and serial numbers for the patient warming devices used in the study described in Legg & Hamer.
31. Model and serial numbers for the patient warming devices used in the study described in Legg, Cannon, & Hamer.
32. Specifications of the ventilation system for the operating room used in the study described in Legg & Hamer.
33. Specifications of the ventilation system for the operating room used in the study described in Legg, Cannon, & Hamer.
34. Specifications, instructions for use, and calibration records for the particle counter used in the study described in Legg & Hamer.
35. Specifications, instructions for use, and calibration records for the particle counter used in the study described in Legg, Cannon, & Hamer.
36. Specifications and instructions for use of the bubble generator used in the study described in Legg & Hamer.
37. Draft protocols for the study described in Legg & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
38. Draft protocols for the study described in Legg, Cannon, & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
39. Final protocols for the study described in Legg & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
40. Final protocols for the study described in Legg, Cannon, & Hamer, including but not limited to the arrangement of the patient, draping, lights, and personnel.
41. Patient warming protocols and warming technologies employed at the Northern General Hospital, Sheffield, UK from 2008 to the present.
42. Orthopaedic infection rates at the Northern General Hospital, Sheffield, UK from 2008 to the present.

Data from and Results of the Studies

43. All raw data generated during the implementation of the study described in Legg & Hamer.
44. All raw data generated during the implementation of the study described in Legg, Cannon, & Hamer.
45. All results from the statistical analysis of raw data from the study described in Legg & Hamer.
46. All results from the statistical analysis of raw data from the study described in Legg, Cannon, & Hamer.
47. Photographs, including time-lapse photography, taken during the implementation of the study described in Legg & Hamer.
48. Photographs, including time-lapse photography, taken during the implementation of the study described in Legg, Cannon, & Hamer.
49. Video or audio recordings made during the implementation of the study described in Legg & Hamer.
50. Video or audio recordings made during the implementation of the study described in Legg, Cannon, & Hamer.
51. Communications between you and A.J. Hamer regarding the results of the study described in Legg & Hamer.
52. Communications between and among you and the other authors of Legg, Cannon, & Hamer regarding the results of the study described in Legg, Cannon, & Hamer.
53. Communications between you and Scott Augustine regarding the results of the study described in Legg & Hamer.
54. Communications between you and Scott Augustine regarding the results of the study described in Legg, Cannon, & Hamer.
55. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Legg & Hamer.
56. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Legg, Cannon, & Hamer.
57. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Legg & Hamer.

58. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Legg, Cannon, & Hamer.

Study Publication

59. All pre-publication drafts and manuscripts of Legg & Hamer.
60. All pre-publication drafts and manuscripts of Legg, Cannon, & Hamer.
61. Communications between you and A.J. Hamer regarding the drafting of Legg & Hamer.
62. Communications between and among you and the other authors of Legg, Cannon, & Hamer regarding the drafting of Legg, Cannon, & Hamer.
63. Communications between you and Scott Augustine regarding the drafting of Legg & Hamer.
64. Communications between you and Scott Augustine regarding the drafting of Legg, Cannon, & Hamer.
65. All communications from reviewers of Legg & Hamer regarding Legg & Hamer.
66. All communications from reviewers of Legg, Cannon, & Hamer regarding Legg, Cannon, & Hamer.

Documents Relating to Consulting Fees (If Any) Received From Scott Augustine, Augustine Biomedical + Design, and/or Augustine Temperature Management LLC

67. Records of consulting fees, expense reimbursement, and other compensation paid to you by Scott Augustine.
68. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Biomedical + Design.
69. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Temperature Management LLC.

Communications with Counsel

70. Communications or correspondence between you and any lawyer or solicitor representing 3M in connection with the subject litigation pending in the United States.
71. Communications or correspondence between you and any lawyer or solicitor representing any plaintiff in connection with the subject litigation pending in the United States.

Appendix B-3
Request for Documents to Paul McGovern, BSc, MBBS, MRCS, PGCME, FHEA

Defendants 3M Company and Arizant Healthcare, Inc. request that the documents described below be produced by Dr. McGovern.

Documents To Be Produced

Dr. McGovern's Background

1. Your curriculum vitae or resume.

Documents Relating to Study Initiation and Protocols, Materials, and Methods

2. Communications between and among you, M. Albrecht, K. Belani, C. Nachtsheim, P. Partington, I. Carluke, and M. Reed regarding the study that was described in the article titled "Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics," published in the Journal of Bone and Joint Surgery (British) 2011 Nov.; 93(11):1537-44 (hereafter "McGovern et al.").
3. Communications between and among you, M. Albrecht, K. Belani, C. Nachtsheim, and M. Reed regarding the study that was described in the article titled "Patient warming excess heat: the effects on orthopedic operating room ventilation performance," published in Anesthesia Analgesia 2013 Aug.; 117(2):406-11 (hereafter "Belani et al.").
4. Communications between and among you, M. Albrecht, O. Kimberger, and M. Reed regarding the study that was described in the article titled "Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions," published in the AANA Journal, 2013 Aug.; 81(4):275-80 (hereafter "Reed et al.").
5. Communications between and among you and the other authors of McGovern et al. on the subject of funding for the study described in McGovern et al.
6. Communications between and among you and the other authors of Belani et al. on the subject of funding for the study described in Belani et al.
7. Communications between and among you and the other authors of Reed et al. on the subject of funding for the study described in Reed et al.
8. Communications between and among you and the other authors of McGovern et al. on the subject of obtaining patient warming devices for the study described in McGovern et al.
9. Communications between and among you and the other authors of Belani et al. on the subject of obtaining patient warming devices for the study described in Belani et al.

10. Communications between and among you and the other authors of Reed et al. on the subject of obtaining patient warming devices for the study described in Reed et al.
11. Communications between and among and you and the other authors of McGovern et al. on the subject of the design of the study described in McGovern et al.
12. Communications between and among and you and the other authors of Belani et al. on the subject of the design of the study described in Belani et al.
13. Communications between and among and you and the other authors of Reed et al. on the subject of the design of the study described in Reed et al.
14. Communications between you and Scott Augustine on the subject of the design of the study described in McGovern et al.
15. Communications between you and Scott Augustine on the subject of the design of the study described in Belani et al.
16. Communications between you and Scott Augustine on the subject of the design of the study described in Reed et al.
17. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in McGovern et al.
18. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Belani et al.
19. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Reed et al.
20. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in McGovern et al.
21. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Belani et al.
22. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Reed et al.
23. Communications between you and Scott Augustine on the subject of funding of the study described in McGovern et al.
24. Communications between you and Scott Augustine on the subject of funding of the study described in Belani et al.
25. Communications between you and Scott Augustine on the subject of funding of the study described in Reed et al.

26. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in McGovern et al.
27. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Belani et al.
28. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Reed et al.
29. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in McGovern et al.
30. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Belani et al.
31. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Reed et al.
32. Communications between you and Scott Augustine regarding the implementation of the study described in McGovern et al.
33. Communications between you and Scott Augustine regarding the implementation of the study described in Belani et al.
34. Communications between you and Scott Augustine regarding the implementation of the study described in Reed et al.
35. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in McGovern et al.
36. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Belani et al.
37. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Reed et al.
38. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in McGovern et al.
39. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Belani et al.
40. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Reed et al.
41. Communications between you and the Northumbria Healthcare NHS Foundation Trust regarding the study described in McGovern et al.

42. Communications between you and the University of Minnesota regarding the study described in Belani et al.
43. Communications between you and the “single hospital in Vienna, Austria” identified in Reed et al. regarding the study described in Reed et al.
44. Model and serial numbers for the patient warming devices used in the study described in McGovern et al.
45. Model and serial numbers for the patient warming devices used in the study described in Belani et al.
46. Model and serial numbers for the patient warming devices used in the study described in Reed et al.
47. Specifications of the ventilation system for the operating room used in the study described in McGovern et al.
48. Specifications of the ventilation system for the operating room used in the study described in Belani et al.
49. Specifications of the ventilation system for the operating room used in the study described in Reed et al.
50. Specifications and instructions for use of the bubble generator used in the study described in McGovern et al.
51. Specifications and instructions for use of the bubble generator used in the study described in Belani et al.
52. Specifications and instructions for use of the equipment used to assess filter efficiency in the study described in Reed et al.
53. Specifications and instructions for use of the particle counter used in the study described in Reed et al.
54. Draft protocols for the study described in McGovern et al.
55. Draft protocols for the study described in Belani et al., including but not limited to the arrangement of draping, lights, and personnel.
56. Draft protocols for the study described in Reed et al.
57. Final protocols for the study described in McGovern et al.
58. Final protocols for the study described in Belani et al., including but not limited to the arrangement of draping, lights, and personnel.

59. Final protocols for the study described in Reed et al.
60. Records regarding changes to the antibiotic and thromboprophylaxis protocols described in McGovern et al.
61. Bacterial screening protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.
62. Patient warming protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.
63. Surgical skin preparation protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.
64. Wound dressing protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.

Data from and Results of the Studies

65. All raw data generated during the implementation of the study described in McGovern et al.
66. Blinded patient data from the study described in McGovern et al.
67. All raw data generated during the implementation of the study described in Belani et al.
68. All raw data generated during the implementation of the study described in Reed et al.
69. All results from the statistical analysis of raw data from the study described in McGovern et al.
70. All results from the statistical analysis of raw data from the study described in Belani et al.
71. All results from the statistical analysis of raw data from the study described in Reed et al.
72. Photographs, including time-lapse photography, taken during the implementation of the study described in McGovern et al.
73. Photographs, including time-lapse photography, taken during the implementation of the study described in Belani et al.
74. Photographs taken during the implementation of the study described in Reed et al.
75. Video or audio recordings made during the implementation of the study described in McGovern et al.

76. Video or audio recordings made during the implementation of the study described in Belani et al.
77. Video or audio recordings made during the implementation of the study described in Reed et al.
78. Communications between and among you and the other authors of McGovern et al. regarding the results of the study described in McGovern et al.
79. Communications between and among you and the other authors of Belani et al. regarding the results of the study described in Belani et al.
80. Communications between and among you and the other authors of Reed et al. regarding the results of the study described in Reed et al.
81. Communications between you and Scott Augustine regarding the results of the study described in McGovern et al.
82. Communications between you and Scott Augustine regarding the results of the study described in Belani et al.
83. Communications between you and Scott Augustine regarding the results of the study described in Reed et al.
84. Communications between you and Augustine Biomedical + Design regarding the results of the study described in McGovern et al.
85. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Belani et al.
86. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Reed et al.
87. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in McGovern et al.
88. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Belani et al.
89. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Reed et al.

Study Publication

90. All pre-publication drafts and manuscripts of McGovern et al.
91. All pre-publication drafts and manuscripts of Belani et al.
92. All pre-publication drafts and manuscripts of Reed et al.
93. Communications between and among you and the other authors of McGovern et al. regarding the drafting of McGovern et al.
94. Communications between and among you and the other authors of McGovern et al. regarding the drafting of Belani et al.
95. Communications between and among you and the other authors of McGovern et al. regarding the drafting of Reed et al.
96. Communications between you and Scott Augustine regarding the drafting of McGovern et al.
97. Communications between you and Scott Augustine regarding the drafting of Belani et al.
98. Communications between you and Scott Augustine regarding the drafting of Reed et al.
99. All communications from reviewers of McGovern et al. regarding McGovern et al.
100. All communications from reviewers of Belani et al. regarding Belani et al.
101. All communications from reviewers of Reed et al. regarding Reed et al.

Documents Relating to Consulting Fees (If Any) Received From Scott Augustine, Augustine Biomedical + Design, and/or Augustine Temperature Management LLC

102. Records of consulting fees, expense reimbursement, and other compensation paid to you by Scott Augustine.
103. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Biomedical + Design.
104. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Temperature Management LLC.

Communications with Counsel

105. Communications or correspondence between you and any lawyer or solicitor representing 3M in connection with the subject litigation pending in the United States.

106. Communications or correspondence between you and any lawyer or solicitor representing any plaintiff in connection with the subject litigation pending in the United States.

US.107059566.01

Appendix B-4
Request for Documents to Mike R. Reed, MD, FRCS

Defendants 3M Company and Arizant Healthcare, Inc. request that the documents described below be produced by Dr. Reed.

Documents To Be Produced

Dr. Reed's Background

1. Your curriculum vitae or resume.

Documents Relating to Study Initiation and Protocols, Materials, and Methods

2. Communications between and among you, P. McGovern, M. Albrecht, K. Belani, C. Nachtsheim, P. Partington, I. Carluke regarding the study that was described in the article titled "Forced-air warming and ultra-clean ventilation do not mix: an investigation of theatre ventilation, patient warming and joint replacement infection in orthopaedics," published in the Journal of Bone and Joint Surgery (British) 2011 Nov.; 93(11):1537-44 (hereafter "McGovern et al.").
3. Communications between and among you, M. Albrecht, K. Belani, C. Nachtsheim, and P. McGovern regarding the study that was described in the article titled "Patient warming excess heat: the effects on orthopedic operating room ventilation performance," published in Anesthesia Analgesia 2013 Aug.; 117(2):406-11 (hereafter "Belani et al.").
4. Communications between and among you, M. Albrecht, O. Kimberger, and P. McGovern regarding the study that was described in the article titled "Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions," published in the AANA Journal, 2013 Aug.; 81(4):275-80 (hereafter "Reed et al.").
5. Communications between and among you, M. Wood, C. Moss, A. Keenan, and D. Leaper regarding the article titled "Infection control hazards associated with the use of forced-air warming in operating theatres," published in the Journal of Hospital Infection, 2014 Nov; 88(3):132-40 (hereafter "Wood et al.").
6. Communications between and among you and the other authors of McGovern et al. on the subject of obtaining patient warming devices for the study described in McGovern et al.
7. Communications between and among you and the other authors of Belani et al. on the subject of obtaining patient warming devices for the study described in Belani et al.
8. Communications between and among you and the other authors of Reed et al. on the subject of obtaining patient warming devices for the study described in Reed et al.

9. Communications between you and Scott Augustine on the subject of the design of the study described in McGovern et al.
10. Communications between you and Scott Augustine on the subject of the design of the study described in Belani et al.
11. Communications between you and Scott Augustine on the subject of the design of the study described in Reed et al.
12. Communications between you and Scott Augustine on the subject of the review criteria for the studies included in Wood et al.
13. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in McGovern et al.
14. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Belani et al.
15. Communications between you and Augustine Biomedical + Design on the subject of the design of the study described in Reed et al.
16. Communications between you and Augustine Biomedical + Design on the subject of the review criteria for the studies included in Wood et al.
17. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in McGovern et al.
18. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Belani et al.
19. Communications between you and Augustine Temperature Management LLC on the subject of the design of the study described in Reed et al.
20. Communications between you and Augustine Temperature Management LLC on the subject of the review criteria for the studies included in Wood et al.
21. Communications between you and Scott Augustine on the subject of funding of the study described in McGovern et al.
22. Communications between you and Scott Augustine on the subject of funding of the study described in Belani et al.
23. Communications between you and Scott Augustine on the subject of funding of the study described in Reed et al.
24. Communications between you and Scott Augustine on the subject of funding of Wood et al.

25. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in McGovern et al.
26. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Belani et al.
27. Communications between you and Augustine Biomedical + Design on the subject of funding of the study described in Reed et al.
28. Communications between you and Augustine Biomedical + Design on the subject of funding of Wood et al.
29. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in McGovern et al.
30. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Belani et al.
31. Communications between you and Augustine Temperature Management LLC on the subject of funding of the study described in Reed et al.
32. Communications between you and Augustine Temperature Management LLC on the subject of funding of Wood et al.
33. Communications between you and Scott Augustine regarding the implementation of the study described in McGovern et al.
34. Communications between you and Scott Augustine regarding the implementation of the study described in Belani et al.
35. Communications between you and Scott Augustine regarding the implementation of the study described in Reed et al.
36. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in McGovern et al.
37. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Belani et al.
38. Communications between you and Augustine Biomedical + Design regarding the implementation of the study described in Reed et al.
39. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in McGovern et al.
40. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Belani et al.

41. Communications between you and Augustine Temperature Management LLC regarding the implementation of the study described in Reed et al.
42. Communications between you and the Northumbria Healthcare NHS Foundation Trust regarding the study described in McGovern et al.
43. Communications between you and the University of Minnesota regarding the study described in Belani et al.
44. Communications between you and the “single hospital in Vienna, Austria” identified in Reed et al. regarding the study described in Reed et al.
45. Model and serial numbers for the patient warming devices used in the study described in McGovern et al.
46. Model and serial numbers for the patient warming devices used in the study described in Belani et al.
47. Model and serial numbers for the patient warming devices used in the study described in Reed et al.
48. Specifications of the ventilation system for the operating room used in the study described in McGovern et al.
49. Specifications of the ventilation system for the operating room used in the study described in Belani et al.
50. Specifications of the ventilation system for the operating room used in the study described in Reed et al.
51. Final protocols for the study described in McGovern et al.
52. Final protocols for the study described in Belani et al., including but not limited to the arrangement of draping, lights, and personnel.
53. Final protocols for the study described in Reed et al.
54. Final criteria for the literature review described in Wood et al.
55. Records regarding changes to the antibiotic and thromboprophylaxis protocols described in McGovern et al.
56. Bacterial screening protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.
57. Patient warming protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.

58. Surgical skin preparation protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.
59. Wound dressing protocols at the Northumbria Healthcare NHS Foundation Trust from 2008 to the present.

Data from and Results of the Studies

60. All raw data generated during the implementation of the study described in McGovern et al.
61. Blinded patient data from the study described in McGovern et al.
62. All raw data generated during the implementation of the study described in Belani et al.
63. All raw data generated during the implementation of the study described in Reed et al.
64. All results from the statistical analysis of raw data from the study described in McGovern et al.
65. All results from the statistical analysis of raw data from the study described in Belani et al.
66. All results from the statistical analysis of raw data from the study described in Reed et al.
67. Photographs, including time-lapse photography, taken during the implementation of the study described in McGovern et al.
68. Photographs, including time-lapse photography, taken during the implementation of the study described in Belani et al.
69. Photographs taken during the implementation of the study described in Reed et al.
70. Video or audio recordings made during the implementation of the study described in McGovern et al.
71. Video or audio recordings made during the implementation of the study described in Belani et al.
72. Video or audio recordings made during the implementation of the study described in Reed et al.
73. Communications between and among you and the other authors of McGovern et al. regarding the results of the study described in McGovern et al.
74. Communications between and among you and the other authors of Belani et al. regarding the results of the study described in Belani et al.

75. Communications between and among you and the other authors of Reed et al. regarding the results of the study described in Reed et al.
76. Communications between and among you and the other authors of Wood et al. regarding the results of the literature review described in Wood et al.
77. Communications between you and Scott Augustine regarding the results of the study described in McGovern et al.
78. Communications between you and Scott Augustine regarding the results of the study described in Belani et al.
79. Communications between you and Scott Augustine regarding the results of the study described in Reed et al.
80. Communications you and Scott Augustine regarding the results of the literature review described in Wood et al.
81. Communications between you and Augustine Biomedical + Design regarding the results of the study described in McGovern et al.
82. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Belani et al.
83. Communications between you and Augustine Biomedical + Design regarding the results of the study described in Reed et al.
84. Communications you and Augustine Biomedical + Design regarding the results of the literature review described in Wood et al.
85. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in McGovern et al.
86. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Belani et al.
87. Communications between you and Augustine Temperature Management LLC regarding the results of the study described in Reed et al.
88. Communications you and Augustine Temperature Management LLC regarding the results of the literature review described in Wood et al.

Study Publication

89. All pre-publication drafts and manuscripts of McGovern et al.
90. All pre-publication drafts and manuscripts of Belani et al.
91. All pre-publication drafts and manuscripts of Reed et al.
92. All pre-publication drafts and manuscripts of Wood et al.
93. Communications between and among you and the other authors of McGovern et al. regarding the drafting of McGovern et al.
94. Communications between and among you and the other authors of Belani et al. regarding the drafting of Belani et al.
95. Communications between and among you and the other authors of Reed et al. regarding the drafting of Reed et al.
96. Communications between and among you and the other authors of Wood et al. regarding the drafting of Wood et al.
97. Communications between you and Scott Augustine regarding the drafting of McGovern et al.
98. Communications between you and Scott Augustine regarding the drafting of Belani et al.
99. Communications between you and Scott Augustine regarding the drafting of Reed et al.
100. Communications between you and Scott Augustine regarding the drafting of Wood et al.
101. All communications from reviewers of McGovern et al. regarding McGovern et al.
102. All communications from reviewers of Belani et al. regarding Belani et al.
103. All communications from reviewers of Reed et al. regarding Reed et al.
104. All communications from reviewers of Wood et al. regarding Wood et al.

Documents Relating to Consulting Fees (If Any) Received From Scott Augustine, Augustine Biomedical + Design, and/or Augustine Temperature Management LLC

105. Records of consulting fees, expense reimbursement, and other compensation paid to you by Scott Augustine.
106. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Biomedical + Design.

107. Records of consulting fees, expense reimbursement, and other compensation paid to you by Augustine Temperature Management LLC.

Communications with Counsel

108. Communications or correspondence between you and any lawyer or solicitor representing 3M in connection with the subject litigation pending in the United States.
109. Communications or correspondence between you and any lawyer or solicitor representing any plaintiff in connection with the subject litigation pending in the United States.

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